

JONATHAN E. FIELDING, M.D., M.P.H. Director and Health Officer

JONATHAN E. FREEDMAN Chief Deputy Director

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www.publichealth.lacounty.gov

December 7, 2010

Herbert Lerner, M.D., Acting Director Division of Reproductive, Gastro-Renal, and Urological Devices Center for Devices and Radiological Health U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Dear Dr. Lerner:

As Health Officer for Los Angeles County, I am requesting the Food and Drug Administration (FDA) to investigate the promotion of the LAP-BAND® Adjustable Gastric Banding System manufactured by Allergan (PMA P000008), as the advertising of this medical device by 1-800-GET-THINTM Weight Loss Centers inadequately informs consumers of potential risks. This warrants review by the FDA particularly if these clinics are considered distributors of the device.

The LAP-BAND® weight loss procedure is marketed directly to consumers in Los Angeles County through billboards, bus placards, and direct mail with slogans such as "Diets fail! The LAP-BAND® works!" (see Attachment). These ads fail to provide the relevant warnings, precautions, side effects, and contraindications related to the procedure. While bariatric surgery is appropriate for certain types of patients, it is not indicated for the vast majority of individuals, and should be reserved for those who have failed other approaches. The LAP-BAND® marketing also impairs our ability to effectively implement public health measures by asserting that traditional weight loss interventions "fail."

Currently, the LAP-BAND® is indicated for weight reduction for severely obese patients with a body mass index (BMI) of at least 40 who have failed more conservative weight-reduction alternatives, or a BMI of at least 35 with one or more severe comorbid conditions, or those who are 100 lbs or more over their ideal weight. Allergan has requested that the FDA approve expansion of the Indication for Use to include patients with a BMI of at least 35, or a BMI of as least 30 with one or more comorbid conditions. While we recognize that approval of the indication will be based on regulatory requirements for safety and effectiveness, we estimate that, once approved, over two million people in Los Angeles County alone could meet the indications for the procedure.



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Misleading advertisements erode the ability of the majority of the public, who are currently either overweight or obese, to fairly consider alternative weight management options, and for "normal" weight individuals to be concerned about behavior that increases risk of weight gain. Given the harms of medical complications and unrealistic expectations resulting from the misleading promotion of this product, I strongly recommend that FDA to take the necessary steps to ensure that 1-800-GET-THIN<sup>TM</sup> Weight Loss Centers' LAP-BAND® promotion does not constitute misbranding of a restricted device.

Sincerely,

Jonathan E. Fielding, M.D., M.P.H.

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Director and Health Officer

JEF:11

Attachment

c: Thomas Abrams, DDMAC
Jeffrey Shuren, M.D., J.D. Director, CDRH
Paul Tilton, Div. of Enforcement A, Ob/Gyn, Gastro. and Urology Devices Branch
Howard Sklamberg, Office of Regulatory Affairs, Office of Enforcement
David E.I. Pyott, Chairman of the Board and Chief Executive Officer, Allergan

Additional Information on the advertising and weight loss centers

The telephone number in the ad, 1-800-GET-THIN™, is for 1-800-GET-THIN™ Weight Loss Centers which has 11 locations in California. 1-800-GET-THIN™ Weight Loss Centers also use the telephone number 1-800-GET-SLIM. Information about the weight loss centers is available from at least four different web addresses including:

- www.1800getthin.com,
- www.1800-get-slim.com,
- · www.weightlosscenters.com, and
- www.topsurgeons.com.

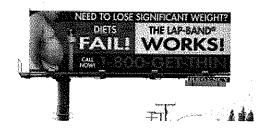
The 1-800-GET-THIN™ Weight Loss Centers websites reference the Allergan LAP-BAND® procedure and link to sites with Allergan LAP-BAND® literature.

The Medical Board of California has taken action against two physicians (named in a Los Angeles Times investigative report, 2/14/2010) affiliated with the weight loss centers by revoking the license of one, and limiting the practice of the other.

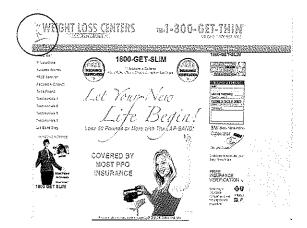
## Billboards





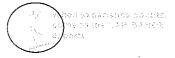


#### Website



Ad

### Lose 50 Pounds or More with the LAP-BAND®!



- ✓ No Hospital Stay
- Covered by PPO Insurance
- ✓ No Stomach Cutting or Stapling
- 📝 100% Reversible & Adjustable
- ✓ No Hunger! Not Another Diet!



## Direct mail





# GALL NOW!

SCHEDULE YOUR APPOINTMENT TODAY WHILE YOUR PPO INSURANCE STILL COVERS THE LAP-BAND!

FREE PPO HEALTH INSURANCE VERIFICATION

GET THE LAP-BAND!

CALL T-800-GET-THIN

Hours: 6:30AM - 10PM + (1-800-953-5000)

BEVERTY HELS: WEST HELS: VALENCIA | PALASSALE | APPLE VALLEY | BAKERSHELD COVENA | SANTA ANA | LONG BEACH | SAN BENJASHBO | SAN BECO





## FREE PPO HEALTH INSURANCE VERIFICATION

FOR SIGNIFICANT WEIGHT LOSS

CALL -800-GET-THIN

Hours: 6:30AM - 10PM \* (1-800-953-5000)

COVINA | SANIA ARIA | LONG BEACH | SAN BERNARDING | SAN INEGO